

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### I. Introduction

The specification has been amended to correct a typographical error. Specifically, the phrase “low specific gravity” has been changed to “high specific gravity.” The original specification supports the revision, for example, at page 1, second paragraph, where small particle LDL is defined as an LDL that “is especially smaller in particle size among LDLs and higher in density than standard LDL.”

Moreover, the specification describes that “the density is below 1.006 for VLDL, 1.029-1.063 for LDL and 1.063-1.21 for HDL” (page 9, lines 8-9) and that “the small particle LDL to be measured...and the specific gravity of which is 1.040-1.063” (*id.*, lines 15-17). Therefore, one skilled in the art would have concluded that small particle LDL has higher specific gravity relative to other LDLs.

Claims 1, 3-27 and 29 have been amended to set forth the claimed subject matter more clearly and to correct the dependency. The original specification supports these revisions, for example, page 12, third paragraph through page 14, third full paragraph. Claims 30-36 have been added with support in the specification, Examples 1-9. Claims 2 and 28 are cancelled without prejudice or disclaimer.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1, 3-27 and 29-36 will be pending.

### II. Formalities

A certified copy of English translation of the priority document, Japanese Patent Application No. 355119/2002, filed December 6, 2002, is submitted herewith to perfect the priority claim in the present application. Therefore, the claims of the present application benefit from a priority date of December 6, 2002.

### III. Objection to the Abstract

The Examiner objected to the abstract for informalities. Accordingly, a new abstract is appended to the end of this response to replace the previously-filed abstract.

#### **IV. Claim Objection**

The Examiner objected to claims 4-9, 12-14, 18-22 and 29 for improper multiple dependency. The claims in question have been amended to correct the multiple dependency, thereby obviating the basis for the objection.

#### **IV. Rejection of Claims under 35 U.S.C. § 112, second paragraph**

The Examiner rejected claims 11, 15-17 and 23-28 for alleged indefiniteness. Applicants respectfully traverse the rejection.

Specifically, the examiner rejected claim 11 for lack of the unit of concentration, claims 15, 23, 25 and 27 for lack of antecedent basis for “the low density lipoprotein,” and claims 25 and 27 for alleged ill-clarity about the lipoprotein measured.

Applicants believe that the rejections under section 112 are overcome in view of the foregoing claim amendments.

#### **V. Rejection of Claims under 35 U.S.C. § 102**

##### **A. Rejection under 35 U.S.C. § 102 (a) over Hirano**

The Examiner rejected claims 1-2, 15 and 17 for alleged anticipation by Hirano *et al.*, *Journal of Lipid Research*, volume 44, 2003. Applicants respectfully traverse the rejection.

The cited reference was published in 2003, after the priority date of the present invention, December 6, 2002, and therefore, is not qualified art under section 102.

##### **B. Rejection under 35 U.S.C. § 102 (b) over Sugiuchi**

The Examiner rejected claims 25 and 27-28 for alleged anticipation by WO 00/17388 (equivalent to U.S. Patent No. 6,794,157) by Sugiuchi. Applicants respectfully traverse the rejection.

Claims 25 and 27 have been amended to recite a kit for measuring small particle LDL, where the kit comprises, *inter alia*, a surface active agent that is selected from the group consisting of polyoxyethylene lauryl ether, polyoxyethylene cetyl ether, polyoxyethylene octylphenyl ether and polyoxyethylene nonylphenyl ether. As described in the specification, the surface active agent is used to eliminate lipoproteins other than LDL from the test sample. See page 13, the fourth paragraph. By contrast, Sugiuchi does not teach a kit comprising the surface active agent to anticipate the claims in question.

C. Rejection under 35 U.S.C. § 102 (b) over Miyauchi

The Examiner rejected claims 25 and 27-28 for alleged anticipation by U.S. Patent No. 5,888,755 to Miyauchi *et al.* Applicants respectfully traverse the rejection.

By the same token, Miyauchi fails to teach the surface active agent as recited in claims 25 and 27 and therefore do not anticipate the claims.

D. Rejection under 35 U.S.C. § 102 (b) over Griffin

The Examiner rejected claim 1 for alleged anticipation by Griffin *et al.*, *Atherosclerosis* 106: 241-253, 1994. Applicants respectfully traverse the rejection.

Claim 2 is not included in this rejection, and claim 1 has been amended to incorporate the salient language from claim 2. Griffin does not teach adding a separation agent comprising a polyanion and a divalent cation to said test sample as prescribed by claim 1 to anticipate claim 1.

E. Rejection under 35 U.S.C. § 102 (a) over JP 2003028882

The Examiner rejected claims 1-3 and 15-17 for alleged anticipation by JP 2003028882 (published January 29, 2003). Applicants respectfully traverse the rejection.

As discussed above, the present application benefits from a priority date of December 6, 2002, which antedates the publication date of the cited reference. Therefore, JP 2003028882 is not qualified art against the present application.

**F. Rejection under 35 U.S.C. § 102 (b) over JP 07294532**

The Examiner rejected claims 1-3 and 15-17 for alleged anticipation by JP 07294532. Applicants respectfully traverse the rejection.

The present invention is directed to quantifying or separating small particle LDL in a test sample. By contrast, JP 07294532 does not relate to small particle LDL, as the Examiner asserts. According to the Examiner, the cited art “teaches a method for the fractionation and measurement of low specific gravity serum lipoprotein based upon precipitation of the lipoprotein in the serum...” (Action, page 6, lines 16-17). As discussed in the foregoing paragraphs, the typographical error in the specification has been corrected. Therefore, one skilled in the art would have understood that the small particle LDL recited in the claims does not belong to the category of “low specific gravity serum lipoprotein,” as disclosed in the prior art.

Moreover, the cited art merely describes that chylomicron, VLDL and LDL can be precipitated by polyanion, divalent cation and monovalent cation. Accordingly, JP 07294532 fails to teach removing lipoproteins other than small particle LDL or precipitating LDLs other than small particle LDL, as recited in claim 1 and 15, respectively.

In view of the foregoing discussions, Applicants respectfully request withdrawal of the anticipation rejection.

**V. Rejection of Claims under 35 U.S.C. § 103 (a)**

The Examiner rejected claims 10-11 and 23-24 for alleged obviousness over JP 07294532 in view of Sugiuchi. Applicants respectfully traverse the rejection.

As discussed above, the “low specific gravity serum lipoprotein” of JP 07294532 is not the same as the small particle LDL recited in the claims. Moreover, the Examiner cites Sugiuchi merely for the alleged teaching of adding PEG to the test sample. Therefore, the combined teaching of JP 07294532 and Sugiuchi fails to render the claims at issue obvious.

The Examiner rejected claim 26 for alleged obviousness over Sugiuchi in view of JP 07294532. Applicants respectfully traverse the rejection.

Claim 26 is dependent from claim 25. As discussed above, Sugiuchi does not teach or suggest the surface active agent recited in claim 25. Furthermore, JP 07294532 is cited for the alleged teaching of a monovalent cation and fails to compensate for the deficiency of Sugiuchi. Therefore, claim 26 is non-obvious in view of the combined teaching of the cited references.

Accordingly, Applicants respectfully request withdrawal of the obviousness rejection.

### CONCLUSION

Applicants believe that the present application is in condition for allowance, and they request an early indication to this effect. Examiner Wallenhorst is invited to contact the undersigned directly, should she feel that any other issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If an extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

Date 15 October 2007

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